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Substitute for form 1449/PTO

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STATEMENT BY APPLICANT**

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Sheet 1 of 1

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| Application Number | 10/051,752 |
| Filing Date | January 16, 2002 |
| First named Inventor | John D. Puskas |
| Group Art Unit | 3766 |
| Examiner name | Carl Hernandez Layno |
| Attorney Docket Number | 065071-9052-04 |

U.S. Patent Documents

| Examiner Initials | U.S. Patent Document Number | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document |
|----------------------|-----------------------------|----------------------------------------------------|------------------------------------------|
| | 5,154,172 | Terry, Jr., et al. | 10/13/1992 |
| | 5,179,950 | Stanislaw | 1/19/1993 |
| | 5,186,170 | Varrichio et al. | 2/16/1993 |
| | 5,188,104 | Wernicke et al. | 2/23/1993 |
| | 5,215,086 | Terry, Jr. et al. | 6/1/1993 |
| | 5,231,988 | Wernicke et al. | 8/3/1993 |
| | 5,235,980 | Varrichio et al. | 8/17/1993 |
| | 5,269,303 | Wernicke et al. | 12/14/1993 |
| | 5,299,569 | Wernicke et al. | 4/5/1994 |
| | 5,335,657 | Terry, Jr. et al. | 8/9/1994 |
| | 5,423,877 | Mackey | 6/13/1995 |
| | 5,707,400 | Terry, Jr., et al. | 1/13/1998 |
| | 5,928,272 | Adkins, et al. | 7/27/1999 |
| | 6,473,644 | Terry, Jr. et al. | 10/29/2002 |
| | 6,587,719 | Barrett et al. | 7/1/2003 |
| | 6,609,025 | Barrett et al. | 7/1/2003 |
| | 6,622,038 | Barrett et al. | 9/16/2003 |
| | 6,622,041 | Terry, Jr. et al. | 9/16/2003 |
| | 6,622,047 | Barrett et al. | 9/16/2003 |
| | 6,721,603 | Zabara et al. | 4/13/2004 |

FOREIGN PATENT DOCUMENTS

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|----------------------|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | AGNEW, William F., et al., "Considerations for Safety with Chronically Implanted Nerve Electrodes, Epilepsia, 31(Suppl. 2), 1990, pp. S27-S32, Raven Press, Ltd., New York. |
| | | BELL, et al., "Inotropic Responses of the Left Ventricle to Changes in Heart Rate in Anesthetized Rabbits," Can. J. Physiol. Pharmacol., 65:179-184. |
| | | BENNETTI, F.J., "Direct Coronary Artery Surgery with Saphenous Venin Bypass Without Either Cardiopulmonary Bypass or Cardiac Arrest, J. Cardiovasc. Surg., 26:217-222. |
| | | BENETTI, et al., "Use of Thoracoscopy and a Minimal Thoracotomy, in Mammary-Coronary Bypass to Left Anterior Descending Artery, Without Extracorporeal Circulation," J. Cardiovasc. Surg., 36:159-161. |
| | | BRODDE, Otto-Erich, et al., "Cardiac Muscannic Receptors Decrease with Age In Vitro and In Vivo Studies," Journal of Clinical Investigation, 1998, Vol. 101, No. 2, pp. 471-478. |
| | | Declaration/Clarification of John D. Puskas, M.D., October 11, 2005. |
| | | DiMARCO, J. P., M.D., et al., "Adenosine: Electrophysiologic Effects and Therapeutic Use for Terminating Paroxysmal Supraventricular Tachycardia," Therapy and Prevention Arrhythmia, Circulation 68, No. 6, 1983, pp. 1254-1263. |
| | | FANNING, et al., "Reoperative Coronary Artery Bypass Grafting Without Cardiopulmonary Bypass," Ann. Thorac. Surg., 55:486-489. |
| | | FREILICH, A., M.D., et al., "Adenosine and its Cardiovascular Effects," American Heart Journal, vol. 123, No. 5, May 1992, pp. 1324-1328. |

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|-------------------------------|--|----------------------------|--|

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|----------------------|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | GORMAN, Christine, et al., "How New Heart-Scanning Technology Could Save Your Life," <u>Time</u> , September 5, 2005, pp. 61 and 67. |
| | | HAGEMAN, G.R., et al., "Direct and Reflex Cardiac Bradycardias From Small Vagal Nerve Stimulations," Am. Heart J., Vol. 89, No. 3, pp. 338-348, 1975 (Abstract Only). |
| | | HAMMOND, Edward J., et al., "Vagus Nerve Stimulation in Humans: Neurophysiological Studies and Electrophysiological Monitoring," <u>Epilepsia</u> , 31 Suppl. 2), 1990, pp. S51-S59, Raven Press, Ltd., New York. |
| | | KLASSEN, et al., "Coronary Venous Pressure and Flow: Effects of Vagal Stimulation, Aortic Occlusion, and Vasodilators," Can. J. Physiol. Pharmacol., 1983, 62:531-538. |
| | | LEVY, M. et al., "Autonomic Control of Cardiac Pacemaker Activity and Atrioventricular Transmission," <u>Journal of Applied Physiology</u> , vol. 27, No. 4, October 1969. |
| | | LOCKARD, Joan S., et al., "Feasibility and Safety of Vagal Stimulation in Monkey Model," <u>Epilepsia</u> , 31(Suppl. 2), 1990, pp. S20-S26, Raven Press, Ltd., New York. |
| | | MOHIUDDIN, S. M., M.D., et al., "Safety of Different Dosages of Intravenous Adenosine Used in Conjunction with Diagnostic Myocardial Imaging Techniques," <u>Pharmacotherapy</u> , 1993, 13(5), pp. 476-480. |
| | | NOBREGA, et al., "Resting and Reflex Heart Rate Responses During Cholinergic Stimulation With Pyridostigmine in Humans," <u>Brazilian J. Med. Biol. Res</u> , Vol. 29, No. 11, pp. 1461-1465, 1996 (Abstract Only). |
| | | NOONAN, David, "And the Beat Goes On," <u>Newsweek</u> , July 11, 2005, pp. 56-57. |

| | | | |
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| Examiner Initials | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published. |
| | | OKAZAWA, M., et al., "Effect of Vagal Stimulations and Parenteral Acetylcholine on Canine Trachealis Muscle Shortening," J. Appl. Physiol., Vol. 75, No. 6, pp. 2463-2468, 1992 (Abstract Only). |
| | | PACE, (on the use of nerve cuff stimulation of the vagal nerves, October 1992, Vol. 15, No. 10, pt. 11, pp. 1543-1630. |
| | | PENRY, J. Kiffin, et al., "Prevention of Intractable Partial Seizures by Intermittent Vagal Stimulation in Humans: Preliminary Results," Epilepsia, 31(Suppl. 2), 1990, pp. S40-S43, Raven Press, Ltd., New York. |
| | | PFISTER, et al., "Coronary Artery Bypass Without Cardiopulmonary Bypass," Ann. Thorac. Surg., 54:1085-92. |
| | | RANDALL, Walter C., PhD., "Parasympathetic Control of the Heart," Chapter 4, Nervous Control of Cardiovascular Function, 1984, pp. 68-94. |
| | | REID, Steven A., "Surgical Technique for Implantation of the Neurocybernetic Prosthesis," Epilepsia, 31(Suppl. 2), 1990, pp. S38-S39, Raven Press, Ltd., New York. |
| | | RUTECKI, Paul, "Anatomical, Physiological, and Theoretical Basis for the Antiepileptic Effect of Vagus Nerve Stimulation," Epilepsia, 31(Suppl. 2), 1990, pp. S1-S6, Raven Press, Ltd., New York. |
| | | TERRY, Reese, et al., "An Implantable Neurocybernetic Prosthesis System," Epilepsia, 31 (Suppl. 2, 1990, pp. S33-S37, Raven Press, Ltd. New York. |
| | | URTHALER, James F., "Experimental Studies on the Pathogenesis of Asystole After Verapamil in the Dog," Am. J. Cardiol., Vol. 44, No. 4, pp. 651-656, 1979 (Abstract Only). |

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|----------------------|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | UTHMAN, Basim M., et al., "Efficacy and Safety of Vagus Nerve Stimulation in Patients with Complex Partial Seizures," Epilepsia, 31(Suppl. 2), 1990, pp. S44-S50, Raven Press, Ltd., New York. |
| | | VALAVANUR, Eur. J Cardio-Thorac Surg, 1996, 10:1058-1063. |
| | | WOODBURY, Dixon M., et al., "Effects of Vagal Stimulation on Experimentally Induced Seizures in Rats," Epilepsia, 31(Suppl. 2), 1990, pp. S7-S19, Raven Press, Ltd., New York. |
| | | WESTABY, S., "Coronary Surgery Without Cardiopulmonary Bypass," British Heart Journal, 73:203-205. |

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